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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/690,825	10/18/2000	Dario C. Altieri	044574-5022-2	3716

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MORGAN LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20004

EXAMINER	
CANELLA, KAREN A	

ART UNIT	PAPER NUMBER
1642	

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17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/690,825	Applicant(s) ALTIERI, DARIO C.	
	Examiner Karen A Canella	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *10 March 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *17,18,80-94,97,101,102 and 104* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) *17* is/are allowed.

6)☐ Claim(s) *18,80-85,88-94,97,101,102 and 104* is/are rejected.

7)☐ Claim(s) *86 and 87* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 September 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). 15, 16
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *attachment.*

DETAILED ACTION

1. After review and reconsideration, the finality of the Office action of Paper No. 13 is withdrawn.

2. Claims 95, 96, 98-100 and 103 have been canceled. Claims 94, 101, 102 have been amended. Claims 17, 18, 80-94, 97, 101, 102 and 104 are pending and under consideration.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

4. Acknowledgement is made to applicants claim to the effective priority date of November 20, 1996 via the provisional application of 60/031, 435. However, upon review of said application it is noted that support is lacking for the specific fragment of SEQ ID NO:4. Accordingly, claim 18 will be given the priority date of the 08/975,080 application, Nov. 20, 1997.

5. Claims 18, 80-85, 88-94, 97, 101, 102 and 104 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

(A) As drawn to proteins which minimally comprise the peptides of SEQ ID NO:4 and SEQ ID NO:3.

Claim 18 is drawn to an isolated polypeptide comprising the sequence of SEQ ID NO:4. SEQ ID NO:4 is a peptide of 20 amino acids derived from residues 65 to 84 of the Survivin protein of SEQ ID NO:34. Claim 97 is drawn to an isolated polypeptide comprising the sequence of SEQ ID NO:3 which is a 17-mer peptide derived from residues 3-18 of SEQ ID NO:34. Both claims encompass a separate genus of proteins which minimally comprise said 20-mer or 17-mer peptides. The claims do not limit the function of the polypeptides which comprise said genuses. It is noted that the abstract of Aziz et al (WO 02/86443 and attached

alignment) disclose a lung tumor associated protein which comprises SEQ ID NO:4; the abstract of Ghosh et al (WO 03/87768 and attached alignment) disclose a mitochondrial associated protein which comprises SEQ ID NO:4; the abstract of Dumas et al (EP 1033401 and attached alignment) disclose human secreted protein having the sequence identifier of 6392 which comprises SEQ ID NO:3; and Bennett et al (US 6,277,640, see attached alignment) disclose a human Her-3 polypeptide sequence which comprises SEQ ID NO:3. The specification lacks written description for the proteins described by either Aziz et al or Ghosh et al or Dumas et al or Bennett et al. The disclosure of SEQ ID NO:3 and SEQ ID NO:4 does not adequately describe either claimed genus because each genus tolerates members which do not have the same functional attributes as SEQ ID NO:34 as evidenced by the disclosures of Aziz et al or Ghosh et al or Dumas et al or Bennett et al.

(B) As drawn to variants polypeptides encoded by polynucleotides which hybridize to the open-reading frame of SEQ ID NO:35.

Claim 80 encompasses a genus of proteins which varying in structure from SEQ ID NO:34. The claim is drawn to an isolated polypeptide encoded by a nucleic acid molecule wherein said polypeptide inhibits cellular apoptosis and wherein the nucleic acid molecule hybridizes to the complement of a nucleic acid molecule consisting of the open reading frame of SEQ ID NO:35. It is noted that the arginine residue at position 37 is not accommodated for in the recited nucleic acid regions. The claim recites conditions selected from the group consisting of (1) washing; (2) hybridization and (3)hybridization and washing. When given the broadest reasonable interpretation, conditions (1) reads on a method where any hybridization condition is carried out with the claimed washing step; and condition (2) reads on a method where any washing step, or no washing step, is carried out with the claimed hybridization step. Thus claim 80 does not serve to limit the structures encompassed by the claim to those structures having similarity to SEQ ID NO:34. It is noted that independent claim 81 specifies that the polypeptide is a mammalian peptide. Said claim is further proof that the genus of polypeptides encompassed by claim 80 varies substantially from the structure of SEQ ID NO:34 and encompasses non-mammalian polypeptides. The specification describes only the human protein SEQ ID NO:34 but does not describe a representative number of non-mammalian or non-human polypeptides which would describe the genus. The disclosure of SEQ ID NO:34 fails to adequately describe

the claimed genus, because the genus tolerates members which differ in structural attributes from SEQ ID NO:34.

(C)As drawn to new matter

Claim 104 embodies the fusion protein of claim 94 wherein said fusion protein further comprises a C-terminal RING finger domain. Claim 94 is dependent in part on claim 80, thus, fusion proteins of the genus of proteins encompassed by claim 80 are within the scope of the claim. The specification states on page 63, lines 23-26 that a Survivin chimeric mutant containing a C-terminal RING finger was made a screened for apoptosis inhibition. This statement does not provide support for a genus of Survivin variants fused to C-terminal RING fingers.

6. Claims 18 and 97 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO:34 and peptides consisting of SEQ ID NO:3, or peptides consisting of SEQ ID NO:3 fused to an immunogenic polypeptide such as KLH or BSA, does not reasonably provide enablement for a peptide consisting only of SEQ ID NO:4 or for a polypeptide comprising SEQ ID NO:4, or polypeptides comprising SEQ ID NO:3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 18 is drawn to polypeptides which minimally comprise SEQ ID NO:4. SEQ ID NO:4 is the amino acid sequence of residues 65-84 of SEQ ID NO:34. The specification teaches that substitution of Ala residues at positions Trp67, Pro73 or Cys84 (residues 3, 9 and 20 of SEQ ID NO:4) result in the complete loss of function of Survivin in transfected cells. However, the specification does not teach the function of the peptide consisting of SEQ ID NO:4, not the function of a polypeptide which minimally comprises SEQ ID NO:4 . Claim 97 is drawn to polypeptides which minimally comprise SEQ ID NO:3. The specification teaches that SEQ ID NO:3 was coupled with KLH and injected into rabbits to produce anti-Survivin antibodies (page 51, lines 20-27). SEQ ID NO:3 is the amino acid sequence of residues 3-18 of SEQ ID NO:34. The specification does not provide any specific functional significance to SEQ ID NO:3 other than the fact that it was selected for the production of an anti-Survivin antibody. The specification does not provide any teaching of how to use the myriad of polypeptides which

comprise either SEQ ID NO:3 or 4, and one of skill in the art would not expect that polypeptides which would minimally comprise either SEQ ID NO:3 or 4 would function as SEQID NO:34 for the following reasons.

It is well known in the art that proteins are folded 3-dimensional structures, the function and stability of which are directly related to a specific conformation (Mathews and Van Holde, Biochemistry, 1996, pp. 165-171). In any given protein, amino acids distant from one another in the primary sequence may be closely located in the folded, 3-dimensional structure (Mathews and Van Holde, Biochemistry, 1996, pp. 166, figure 6.1). The specific conformation of a protein results from non-covalent interactions between amino acids, beyond what is dictated by the primary amino acid sequence. A different amino acid sequence surrounding SEQ ID NO:4 can potentially radically alter the three dimensional structural environment in which the given fragment is located (Matthews, B. Genetic and Structural Analysis of the Protein Stability Problem, In: Perspectives in Biochemistry, 1989, Vol. 1, pp. 6-9, Ed. Hans Neurath, especially page 6, second column, first paragraph) thus, the consequences of the altered sequence environment cannot be predicted. Further, it is noted that deletion of the 40 carboxyl terminal residues of Survivin dramatically decreased the anti-apoptotic function of Survivin (page 70, line 27 to page 71, line 4), demonstrating that the sequence context of SEQ ID NO:4 regulates the overall function of the molecule Additionally, it is recognized in the art that protein function is context dependent, and cellular aspects, such as membrane anchorage, protein activation and sub-cellular location must be considered with respect to protein function in addition to molecular aspects (Bork, Genome Research, 1998, V0l. 10, pp. 398-400, p. 398, second column, lines 19-22 under the heading "Limitations in the Total Knowledge Base of Protein Function"). Due to the unreliability of the art and the lack of teachings in the specification which would remedy said unreliability, one of skill in the art would be forced into undue experimentation in order to use the broadly claimed polypeptides.

7. Claims 80-82 and 92 are rejected under 35 U.S.C. 102(b) as being anticipated by Roy et al (Cell, 1995, Vol. 80, pp. 167-178, reference of the IDS filed October 18, 2000) as evidenced by NCBI Conserved Domain Summary of NAID. The specific embodiments of claims 80-82 are set forth above. Claim 92 embodies the polypeptide of claim 80 wherein said polypeptide

comprises a BIR domain. For the reasons set forth above, claim 80 is not limited by similarity in structure to SEQ ID NO:34. Accordingly claims 80-82 are rejected over Roy et al who disclose the NAID human polypeptide which inhibits cellular apoptosis, wherein said NAID polypeptide is lacking a C-terminal RING finger(as corroborated by the specification on page 14, lines 10-14 and 25-27). The NAID polypeptide comprises a BIR domain as evidenced by the attached NCBI Conserved Domain Summary of NAID (gi: 2135814) which indicates the presence of BIR domains at "KOG1101" (www.ncbi.nlm.nih.gov, visited December 18, 2003).

8. Claims 86 and 87 are objected to for being dependent on rejected claim 80.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308 8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308 3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308 0196.

Karen A. Canella

Karen A. Canella, Ph.D.
Primary Examiner, Group 1642
12/18/03